MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/12-24-56

RECALL OF SUBSTANDARD FOLIC ACID TABLET BATCHES (490, 612) MANUFACTURED BY M/S ZAFA PHARMACEUTICAL LABORATORIES (PVT.) LTD, KARACHI.

Date: 18th December, 2024

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

Alert Summary:

The Provincial Inspector of Drugs of various districts of Balochistan collected the samples of Folic acid Tablet and sent for test / analysis. The Drug Testing Laboratory, Quetta has declared following batches of Folic acid Tablet, manufactured by M/s Zafa Pharmaceutical Laboratories (Pvt.) Ltd, Karachi, as of substandard quality based on uniformity of weight.

S#	Product Name	Composition	Batch details	Manufactured by
01	Tablet Folic Acid Reg. No. 000859	Folic acid	Batch No. 490 Batch No. 612	M/s. Zafa Pharmaceutical Laboratories (Pvt.) Ltd. 4/1, A&B, Block-21, Federal "B" Industrial Area, Karachi-75950

Risk Statement:

Folic Acid Tablets not complying with the uniformity of weight specification could result in inconsistent dosages of the active pharmaceutical ingredient (API), potentially leading to reduced therapeutic efficacy or an increased risk of adverse effects in patients.

Action initiated: -

The field force under administrative control of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batch from the market.

Advice for Pharmacies/Medical stores: -

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned product. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase surveillance in the market to ensure the effective recall of defective products(s).

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of mentioned products. Adverse reactions or quality problems experienced with the use of above mentioned product are to be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link.

Advice for Consumers / general public: -

Consumers should stop using products bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

Drug Regulatory Authority of Pakistan
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